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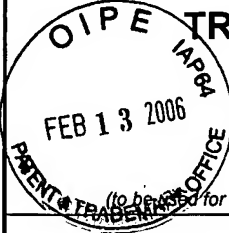
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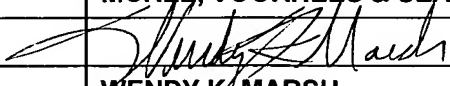
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	<b>TRANSMITTAL FORM</b>	
	Application Number	10/007,866
	Filing Date	December 6, 2001
	First Named Inventor	KUMAR, Vijay
	Art Unit	1623
	Examiner Name	WHITE, EVERETT NMN
Total Number of Pages in This Submission		24
Attorney Docket Number		P04829US1

ENCLOSURES (check all that apply)		
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm Name	MCKEE, VOORHEES & SEASE, P.L.C., CUSTOMER NO. 22885		
Signature			
Printed Name	WENDY K. MARSH		
Date	2/13/06	Reg. No.	39,705

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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IN RE: KUMAR, Vijay et al.	)
	) APPEAL NO. _____
SERIAL NO: 10/007,866	)
	)
FOR: BIODEGRADABLE OXIDIZED	)
CELLULOSE ESTERS	)
	) BRIEF ON APPEAL
FILED: December 6, 2001	)
	)
GROUP ART UNIT: 1623	)

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To the Commissioner of Patents and Trademarks  
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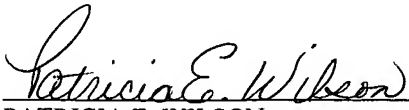
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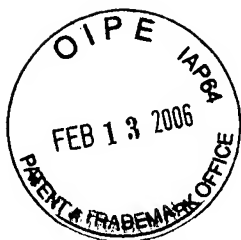
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**I. INTRODUCTION**

This is an Appeal of the Final Rejection dated November 1, 2005, finally rejecting claim 36. The appealed claim 36 is set forth in an attached Appendix.

**II. REAL PARTY IN INTEREST**

This application has been assigned to University of Iowa Research Foundation, an Iowa corporation, having an address of 1000 Oakdale Campus #214 TIC, Iowa City, Iowa 52242-5000. The Assignment was recorded at reel 012649, frame 0036 on February 27, 2002.

**III. RELATED APPEALS AND INTERFERENCES**

None.

**IV. STATUS OF CLAIMS**

Claims 1-35 were originally submitted in the application dated December 6, 2001. In response to an office action dated July 24, 2003, Appellant canceled claims 1-6, amended claims 7-11, 13, and 16, and added claims 36-37. In response to a final office action dated March 9, 2004, Appellant filed a Request for Continued Examination (RCE) requesting entry of an amendment after final rejection withdrawing claims 13-34, canceling claim 37, and amending claims 7-12 and 35-36. In response to an office action dated March 25, 2005, Appellant withdrew claims 13-21 and 23-34, canceled claim 35, amended claim 36, and added claim 38. The claim here appealed is claim 36, as set forth in an attached Appendix.

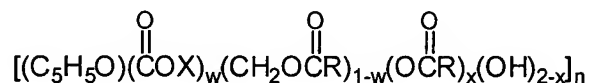
**V. STATUS OF AMENDMENTS**

No amendments were filed in Response to the Final Rejection dated November 1, 2005. A Notice of Appeal was timely filed on December 13, 2005.

## VI. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 36 relates to a biodegradable, oxidized cellulose ester of either general formula I or II:

I.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH<sub>4</sub>, and NEt<sub>3</sub>H;

whereby R is (CH<sub>2</sub>)<sub>n</sub>COOH, where n is 2 to 4;

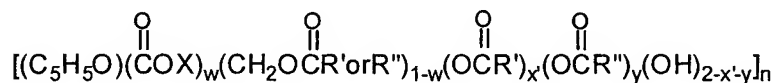
w is 0.1-1.0;

x is 0.1-2.0; and

n is 30-1500.

and

II.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH<sub>4</sub>, and NEt<sub>3</sub>H;

R' and R'' are each selected from the group consisting of: H; CF<sub>3</sub>; (CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, where n is from 0 to 18; (CH<sub>2</sub>)<sub>n</sub>COOH, where n is from 1 to 8; CY=CZCOOH, where Y and Z are

independently selected from the group consisting of hydrogen, methyl, branched alkyl having from 1 to 20 carbon atoms and from one to three *cis* or *trans* double bonds; branched alkenyl having from 1 to 20 carbon atoms and having from one to three *cis* or *trans* double bonds; CY-CH<sub>2</sub>, where Y is H, methyl, or phenyl; CH=CHY, where Y is C<sub>6</sub>H<sub>5</sub>; CH=CYCOOH, where Y is H or CH<sub>3</sub>; (CH<sub>2</sub>)<sub>8</sub>CH=CH(CH<sub>2</sub>)<sub>8</sub>CH<sub>3</sub>; or C<sub>6</sub>H<sub>(2-6)</sub>(COOH)<sub>0-4</sub>, CH<sub>2</sub>CH(COOH)CH<sub>2</sub>-COOH;

w is 0.1-1.0;

x' is 0.1-1.9;

y is 0.1-1.9; and

n is 30-850.

(Specification, page 6, lines 24 to page 8, line 6). The biodegradable oxidized cellulose ester of the invention has an acid number of at least 133. (Specification, page 13, line 26).

The oxidized cellulose esters of the invention are soluble in aqueous alkaline solutions, water and/or common organic solvents. (Specification, page 5, lines 22-27). In comparison to previously made oxidized cellulose esters, the products of this invention offer a new class of biodegradable polymers that may be used as biomaterials and as drug carriers in medicine, pharmaceuticals, agriculture, and veterinary fields. (Specification, page 5, line 29 to page 6, line 1). In addition, these compounds are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer. (Specification, page 6, lines 1-3).

No means plus function or set plus function elements are identified in the claim on appeal.

## **VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

A. Claim 36 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

B. Claim 36 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Bogan et al., U.S. Patent No. 4,590,265.

## VIII. ARGUMENT

### A. **Rejection Under 35 U.S.C. § 112, First Paragraph**

Claim 36 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This rejection should be withdrawn.

#### 1. Legal Standard for New Matter

35 U.S.C. § 112, first paragraph, forbids the inclusion of subject matter into a patent application that, "was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." See MPEP § 706.03(c). 35 U.S.C. § 132 and MPEP § 706.03(o) further provide that subject matter that was not disclosed in the original application that is later added to a claim is considered "new matter." Such a claim is rejected on the ground that it recites elements without support in the original disclosure. MPEP § 706.03(c).

It is well established that under 35 U.S.C. § 132, subsequent clarification of or a change in an original disclosure does not necessarily make that original disclosure fatally defective. Application of Nathan, 328 F.2d 1005, 1006 (C.C.P.A. 1964). For instance, amendatory material concerned with an inherent characteristic of an illustrative product of the applicant's invention already sufficiently identified in the original disclosure as filed is not prohibited by statute. Id. at 1009. For example, in the Nathan case, the C.C.P.A. (predecessor to the Federal Circuit) reversed the decision of the Examiner and the Board refusing entry of amendatory material designating the 2-halo substituent of the compounds disclosed as alpha oriented as lacking basis in the original disclosure. Id. In this respect, the Court held that the amendment was merely a statement of an inherent property of the material originally disclosed. Id. The Court cited Ex parte Davisson and Finlay, 133 USPQ 400, 402, as an analogous situation whereby the examiner has entered an amendment reciting the optical rotation data and elemental analysis of the sulfate of a claimed substance as well as the spectroscopic characteristics of the claimed substance, "apparently regarding them as a

statement of inherent properties of the material adequately disclosed" in an original disclosure. Id.

Similarly, in Regents of the University of New Mexico v. Knight, 321 F.3d 1111, 1122 (Fed. Cir. 2003), the Court noted:

From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing. The graphic formulae, and the chemical nomenclature, the systems of classification and study such as the concepts of homology, isomerism, etc., are mere symbols by which compounds can be identified, classified, and compared. But a formula is not a compound and while it may serve in a claim to identify what is being patented, as the metes and bounds of a deed identify a plot of land, the thing that is patented is not the formula but the compound identified by it....

Based on this observation, the Court held that amendments changing chemical structures to more accurately describe the vitaetheine inventions correctly were not new matter, and that the district court did not err in its holding to that effect. Id.

2. The Addition of an Inherent Feature of the Compounds of Claim 36 Does Not Constitute New Matter

In their amendment dated August 25, 2005, Appellants amended claim 36 to provide that the described compounds have an acid number of at least 133. Appellants noted at the time of amendment that literal support for the limitation was found in Example 1, p. 13, line 26 of the specification whereby it states that the starting material for synthesis of the compound in the example has a carboxylic content of 13.7%. (8/25/05 amendment, p. 10). The resulting compound has a carboxylic content of 10.57%, which directly converts to an acid number of 133.9. (8/25/05 amendment, p. 10).

In this case, the Examiner argues that there is no support in the original specification for the text, "said biodegradable oxidized cellulose ester having an acid number of at least 133." (Nov. 1, 2005 Office Action, p. 2, para. 5). In this regard, the Examiner argues that Example 1 is insufficient documentation for support of the acid number claim limitation on



since Example 1 does not disclose the carboxylic content of the resulting compound thereof and does not set forth the acid number of the resulting compound. (11/1/05 Office Action, p. 3). However, the amendatory material presented in this case is directly analogous to that presented in the Nathan and Knight cases described above. Specifically, the acid number of Appellant's claimed compounds merely identifies an inherent characteristic of the preferred compounds specifically described in Example 1 of the original disclosure. As noted by the Federal Circuit in Knight, the acid number of Appellant's preferred compounds as specifically claimed is inseparable from the claimed compounds and all of their properties. Thus, the addition of the acid number to claim 36 does not constitute new matter under 35 U.S.C. § 112, first paragraph, and this ground of rejection should be reversed.

**B. Rejection Under 35 U.S.C. § 102(b), Anticipation by Bogan et al., U.S. Patent No. 4,590,265**

Claim 36 was rejected under 35 U.S.C. 102(b) as being anticipated by Bogan et al., U.S. Patent No. 4,590,265. This rejection should be withdrawn.

**1. The Law of Anticipation**

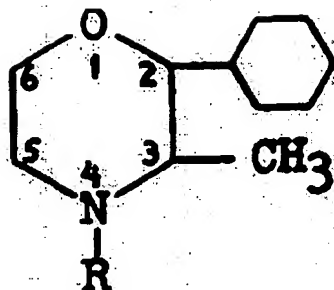
A rejection for anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention. Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984). Further, the reference must generally place the needed subject matter supporting the anticipation rejection in the public domain before the date of invention. In re Zenitz, 333 F.2d 924, 142 USPQ 158, 160 (C.C.P.A. 1964). It follows from this second element that a reference does not legally anticipate the claimed subject matter if it is found not to be sufficiently enabling, in other words, if it does not place the subject matter of the claims within the possession of the public. In re Wilder, 429 F.2d 447, 166 USPQ 545 (C.C.P.A. 1970).

2. Bogan Does Not Teach a Compound Having the Structure or Properties of the Claimed Invention, and Therefore Does Not Anticipate

The Examiner states that Bogan et al. disclose a chemical modification of a cellulose ester by oxidizing the primary hydroxyl group at the C<sub>6</sub> position of the anhydroglucose ring of the cellulose ester to produce a carboxylated cellulose ester which meets the carboxyl content set forth in the instant claims. (March 25, 2005 Office Action, p. 4). The Examiner further states that the structure of the carboxylated cellulose acetate butyrate at the bottom of column 16 of the Bogan et al. patent anticipates the oxidized cellulose ester of formula II set forth in claim 36 when X represents H, when R' and R" represent (CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, n is 0 or 2; when w is 1; and when x' and y are 0.1-1.9. (3/25/05 Office Action, p. 4).

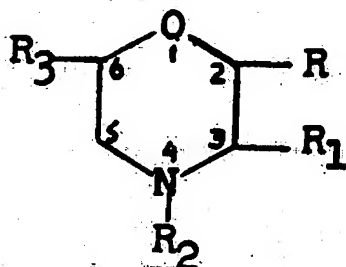
A rejection under 35 U.S.C. § 102(b) for anticipation, such as made by the Examiner in the instant case, necessarily implies that the invention sought to be patented has been, "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States," and therefore is not "new" - that there are no differences between what is claimed and what is disclosed in the prior art. Bearing this legal standard in mind, it is apparent that Bogan does not specifically name, describe or claim any particular, individual compound anticipating Applicant's claims, nor is there any suggestion by Bogan that any of its disclosed compounds is biodegradable, and therefore capable of being used for any of Applicant's intended purposes, for example, as a monolithic transparent film or biodegradable film coating.

The facts at hand are analogous to those presented in Application of Kalm, 378 F.2d 959 (CCPA 1967), a case of binding authority in this matter (a copy of which is enclosed for the Examiner's convenience). In Kalm, the claimed invention related to particular morpholine derivatives of the formula:

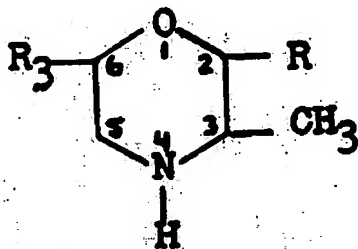


wherein R for purposes here is lower alkyl, being so defined in claim 1 and 2. Kalm, 378 F.2d at 960. Claim 3 was directed to the specific compound 2-cyclohexyl-3, 4-dimethylmorpholine. Id. According to the specification, Kalm's compounds were described as being useful as "selective central nervous system [CNS] depressants - being potent barbiturate potentiators." (Emphasis supplied). Id. According to Siemer, the compounds he disclosed had "a most marked anti-depressive action." Id. at 961.

The examiner rejected claims 1-3 under 35 U.S.C. § 102(e) as being anticipated by the Siemer patent, which disclosed a process for the preparation of compounds of the generic formula:



where R is phenyl or cyclohexyl, R<sub>1</sub> is lower alkyl, and R<sub>2</sub> and R<sub>3</sub> may be hydrogen or lower alkyl, as well as a "one step" process for preparing compounds of the formula:



Kalm, 378 F.2d at 960-61.

The CCPA (predecessor to the Federal Circuit) reversed the examiner and Board's rejection of the claims 1-3 under Section 102, stating that there appeared to be "no question that the Siemer patent does not specifically name, describe or claim any particular, individual compound anticipating appellant's claims, nor is there any suggestion by Siemer that any of his disclosed compounds is capable of depressing the central nervous system. Kalm, 378 F.2d 959, 962 (CCPA 1967). The Court noted that it was the Patent Office's position that Kalm's claimed compounds fell within the scope of the "genus" disclosed by Siemer. Id. at 962-63. The Court disagreed. Instead, the Court determined that Siemer's genus was limited to compounds possessing properties "diametrically opposite" to the properties possessed by Kalm's genus of compounds. Id. at 963. The Court added:

While it is not necessary that a reference disclose every property or attribute of a composition of matter to be a valid anticipation, appellant has found properties for his claimed compounds which are totally incompatible and inconsistent with, not merely complementary or in addition to, those attributed by Siemer to his compounds. It is our view that Siemer never intended to, nor does he, disclose compounds within the scope of appellant's claims.

Id.

In the present application, the Examiner argues that the compound displayed at the bottom of column 16 of Bogan discloses each and every limitation of one of Appellants' formula II species. (3/25/05 Office Action, p. 4). The Examiner makes this rejection even though the compound displayed is described as being only a "segment" of the final carboxylated product achieved when cellulose acetate butyrate is employed as the starting material. (Col. 16, lines 47-50). The final carboxylated product is not biodegradable, unlike Appellants' claimed compounds. (Supp. Decl. V. Kumar, para. 10-11, Exh. 2 to the brief). As noted on pp. 3-4 of the specification, Bogan's compounds are synthesized by ozonolysis of cellulose esters, resulting in non-biodegradable carboxylated cellulose esters.

Furthermore, Applicants have amended claim 36 to provide that the biodegradable compounds have an acid number of at least 133. In contrast, Bogan's compounds, including

the compound shown at the bottom of column 16, do not have an acid number of above 50, with 15-25 being the preferred acid number range. (Col. 15, lines 42-47).

The Examiner argues that Appellants' point that the entire Bogan compound is not biodegradable is not relevant, "since the rejection of the instant claims is based only on the structure at the bottom of column 16 of the Bogan et al. patent." (Office Action, p. 6). The Examiner cannot consider only a portion of the entire compound for purposes of the anticipation analysis and pretend that the rest of the compound does not exist simply because the patentee chose to not to illustrate the remaining portion of that particular compound. The reference must be considered for all that it actually teaches and discloses to persons skilled in the art, and that is a non-biodegradable, carboxylated cellulose ester. See e.g. Bausch & Lomb, Inc., v. Barnes-Hind/Hydrocurve Inc., 796 F.2d 443, 448, 230 USPQ 416, 419 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987); In re Kamm, 452 F.2d 1052, 1057, 172 USPQ 298, 301-02 (CCPA 1972).

Here, it is the Examiner's position that Bogan's compound segment falls within the scope of the "genus" disclosed by Appellants. This is legally inconsistent, however, with the Federal Circuit precedent cited above, since Bogan is limited to compounds possessing properties "diametrically opposite" to the properties possessed by Appellants' genus of compounds, i.e. non-biodegradable compounds having an acid number of 50 or less versus Appellants' biodegradable compounds having an acid number of at least 133. As in the Kalm case, Appellants have discovered properties for their claimed compounds which are totally incompatible and inconsistent with, not merely complementary or in addition to those attributed by Bogan to his compounds. Bogan never intended to, nor does he disclose compounds within the scope of Appellants' claims. For all of these reasons, claim 36 is not anticipated by Bogan.

Claim 36 is also not rendered obvious by Bogan. In this respect, there is no teaching or suggestion in Bogan to prepare biodegradable oxidized cellulose esters having an acid number of 133 or above.

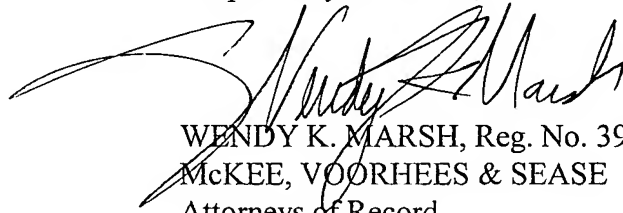
For all of the above-stated reasons, the rejection of claim 36 under 35 U.S.C. § 102(b) is legally unsupported and, accordingly, should be reversed.

**IX. CONCLUSION**

For the above-stated reasons, it is submitted that the claims are in a condition for allowability. The decision of the Examiner, therefore, should be reversed and the case allowed.

Enclosed herein please find the Appeal Brief and required fee of \$250.00. If this amount is not correct, please consider this a request to debit or credit Deposit Account No. 26-0084 accordingly.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Wendy K. Marsh", is written over the typed name and firm name.

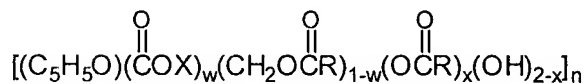
WENDY K. MARSH, Reg. No. 39,705  
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Attorneys of Record  
CUSTOMER NO. 22885

801 Grand - Suite 3200  
Des Moines, Iowa 50309-2721  
515-288-3667

## X. APPENDIX - CLAIMS

36. A biodegradable, oxidized cellulose ester having the following general formula I or II:

I.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH<sub>4</sub>, and NEt<sub>3</sub>H;

whereby R is (CH<sub>2</sub>)<sub>n</sub>COOH, where n is 2 to 4;

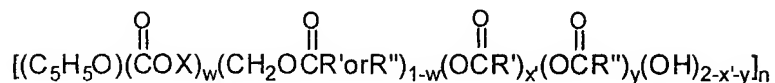
w is 0.1-1.0;

x is 0.1-2.0; and

n is 30-1500.

and

II.



wherein:

X is selected from the group consisting of H, Na, K, Ca, NH<sub>4</sub>, and NEt<sub>3</sub>H;

R' and R'' are each selected from the group consisting of: H; CF<sub>3</sub>; (CH<sub>2</sub>)<sub>n</sub>CH<sub>3</sub>, where n is from 0 to 18; (CH<sub>2</sub>)<sub>n</sub>COOH, where n is from 1 to 8; CY=CZCOOH, where Y and Z are

independently selected from the group consisting of hydrogen, methyl, branched alkyl having from 1 to 20 carbon atoms and from one to three *cis* or *trans* double bonds; branched alkenyl having from 1 to 20 carbon atoms and having from one to three *cis* or *trans* double bonds; CY-CH<sub>2</sub>, where Y is H, methyl, or phenyl; CH=CHY, where Y is C<sub>6</sub>H<sub>5</sub>; CH=CYCOOH, where Y is H or CH<sub>3</sub>; (CH<sub>2</sub>)<sub>8</sub>CH=CH(CH<sub>2</sub>)<sub>8</sub>CH<sub>3</sub>; or C<sub>6</sub>H<sub>(2-6)</sub>(COOH)<sub>0-4</sub>, CH<sub>2</sub>CH(COOH)CH<sub>2</sub>-COOH;

w is 0.1-1.0;

x' is 0.1-1.9;

y is 0.1-1.9; and

n is 30-850;

said biodegradable oxidized cellulose ester having an acid number of at least 133.



**XI. EVIDENCE APPENDIX**

<u>Exhibit</u>	<u>Description</u>
1	Rule 132 Declaration of Dr. Vijay Kumar, entered in the record by the Examiner along with Appellants' October 24, 2003 Amendment.
2	Supplemental Rule 132 Declaration of Dr. Vijay Kumar, entered in the record by the Examiner along with Appellant's December 10, 2004 Request for Continued Examination (RCE).

## **XII. RELATED PROCEEDINGS APPENDIX**

None.



## PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : KUMAR, Vijay  
SERIAL NO : 10/007,866  
FILED : December 6, 2001  
TITLE : BIODEGRADABLE OXIDIZED CELLULOSE ESTERS

Grp./A.U. : 1623  
Examiner : White, E.  
Conf. No. : 6560  
Docket No. : P04829US1

### RULE 132 DECLARATION OF DR. VIJAY KUMAR

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.
2. I have obtained bachelor of science degrees in chemistry, zoology, and botany from Kanpur University in India. I received a master of science degree in chemistry from Lucknow University in 1972, and a Ph.D. degree in chemistry from Lucknow University in 1976, and another Ph.D. from Concordia University in Montreal in 1981. My postdoctoral work has been in the areas of pharmaceuticals and chemistry.
3. From 1992-1996, I was a clinical assistant professor professor and from 1996-2002 an assistant professor in the pharmaceuticals division of the College of Pharmacy, University of Iowa. From 2002 to present I have been an associate professor of the pharmaceuticals in College of Pharmacy, University of Iowa.

4. I have conducted and supervised numerous pharmaceutical research projects since 1993. These projects have dealt primarily with pharmaceutical excipients and formulation techniques.

5. My current research has focused on carbohydrate polymers, especially cellulosic polymers, and their uses as pharmaceutical excipients, drug carriers, and biomaterials, biodegradable delivery systems, tissue engineering, interpolymer complexes, and drug-excipients.

6. I understand that the Examiner has rejected claims 1-12 under 35 U.S.C. 102(b) as being anticipated by Diamantoglou et al. (U.S. Pat. No. 5,008,385). The Examiner's contention that the cellulose derivatives of Diamantoglou anticipate the oxidized cellulose esters of the claimed invention is incorrect.

7. Diamantoglou discloses cellulose esters. Diamantoglou does not, however, disclose oxidized cellulose esters, as claimed in the present invention.

8. The polymers listed in the Diamantoglou patent describe cellulose derivatives containing carboxylic acid groups that are not derived from cellulose but introduced in cellulose as part of substituents. In other words, the carboxylic acid groups in cellulose derivatives are not directly linked to the cellulose backbone, but instead are linked to the side chains (or substituents). This is in contrast to the oxidized cellulose esters of the claimed invention whereby the carboxylic acid groups are an integral part of the oxidized cellulose, the starting material used to prepare the esters of the claimed invention. The carboxylic acid groups in the cellulose backbone (at carbon six position) results from an oxidation reaction.

9. Because the carboxylic acid groups are not directly linked to the cellulose backbone, the water-insoluble, fibrous, cellulose esters of Diamantoglou are not biodegradable, and therefore not useful for the purposes of the claimed invention, which include use as film-forming agents, drug carriers, and immobilizing matrix in the development of biodegradable controlled and/or sustained release pharmaceutical, agricultural, and veterinary compositions. In fact, the cellulose derivatives of Diamantoglou are used primarily as fibers and membranes in hemodialysis. (Col. 1, lines 8-10).

10. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Date: 10/23/03

Vijay Kumar  
Dr. Vijay Kumar

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT : KUMAR, Vijay  
SERIAL NO : 10/007,866  
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Grp./A.U. : 1623  
Examiner : White, E.  
Conf. No. : 6560  
Docket No. : P04829US1

**SUPPLEMENTAL RULE 132 DECLARATION OF DR. VIJAY KUMAR**

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.
2. The present invention describes for the first time the synthesis of biodegradable oxidized cellulose esters.
3. In comparison to previously made oxidized cellulose esters, the products of this invention offer a new class of biodegradable polymers that undergo hydrolysis by enzymatic and/or chemical means *in vivo* and *in vitro*. They may therefore be used as biomaterials and as drug carriers in medicine, pharmaceuticals, agriculture, and veterinary fields.
4. In addition, these oxidized cellulose esters are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer.

5. While others in the art have successfully synthesized carboxylated cellulose esters, such compounds are not biodegradable.

6. Studies show that the carboxyl content and degree of polymerization (DP) of oxidized cellulose play important roles in the degradation of oxidized cellulose *in vitro* and *in vivo*. In general, the higher the carboxyl content, or the lower the DP, the faster the rate of degradation of oxidized cellulose.

7. Compared to other biodegradable polymers, oxidized cellulose has received little consideration as a potential biomaterial or drug carrier. This is because it is practically insoluble in organic solvents and water, and hence, poses little or no formulation flexibility.

8. Recently, U.S. Patent No. 5,973,139 (Lee et al.) disclosed a process for producing carboxylated cellulose esters using oxidized cellulose materials containing about 0.14-0.3% w/w of carboxylic content. In this process, the starting cellulose source is first esterified and then hydrolyzed to give the product. The carboxylated cellulose esters prepared by this method are useful in the development of coating formulations that can be applied to paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

9. Another previous method in the art for preparing carboxylated cellulose esters uses cellulose acetate butyrate as a starting material. The carboxylic groups are then introduced by treating the polymer with ozone. The disadvantage to the carboxylated cellulose esters prepared according to this method, however, is that they are not biodegradable.

10. The method referenced in paragraph 9 is exactly the method by which the carboxylated cellulose esters of Bogan et al. are prepared, i.e. cellulose acetate butyrate is reacted with ozone. Thus, the non-biodegradable cellulosic polymers of Bogan et al. are inherently different from that of the claimed invention.

11. The non-biodegradability of the polymers of Bogan et al. is also illustrated by the intended uses of their compositions. Specifically, the Bogan polymers are intended for use as pigment dispersions (Col. 17, line 44), metal coatings (Col. 18, line 34), ink compositions (Col. 20, line 51), and wood coatings (Col. 22, line 9). One skilled in the art

would realize that such products should not be biodegradable since they must remain intact in order to exhibit permanent sealing/protective qualities.

12. The oxidized cellulose esters of the claimed invention are further distinguished from those of Bogan et al. since they do not include lactone functional groups. Bogan et al. note that their carboxylated cellulose esters including the acetates, butyrates and propionates (termed "XAE") contain a lactone level of from about  $4.52 \times 10^{-5}$  to about  $6.13 \times 10^{-4}$  moles of lactone moiety per gram of XAE. In contrast, Applicants' oxidized cellulose esters do not include lactone moieties, as evidenced by the claimed structures.

13. The Bogan et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

14. The compositions of Lee et al. also do not read on Applicants' claimed compounds since the Lee compounds are not biodegradable.

15. The non-biodegradability of the Lee et al. compounds is evidenced by the low carboxylic content of its compounds (0.14-0.3% w/w) as well as the intended uses of the compounds. More specifically, the intended uses of the Lee compounds, similar to those of Bogan et al., include coating formulations for paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

16. The Lee et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

17. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified



statement is directed.

Date: 7/6/04

Vijay Kumar  
Dr. Vijay Kumar